K083338

510(k) Summary

FEB - 2 2009

Company Name:	SeaSpine, Inc. 2302 La Mirada Drive Vista, CA 92081
Contact Person:	Ethel Bernal Regulatory Affairs Manager E-mail: ebernal@seaspine.com Phone: (760) 727-8399 x218, Fax: (760) 727-8809
Date Prepared:	November 10, 2008
Trade Name:	Cardiff™
Common Name: Classification Name:	Anterior Cervical Plate System Spinal Intervertebral Body Fixation Orthosis 21 CFR 888.3060, Product Code: KWQ, Class II Orthopedic Review Committee
Device Description:	The Cardiff™ Anterior Cervical Plate (ACP) System is intended for anterior interbody screw fixation of the cervical spine only. The Cardiff™ ACP System components are temporary implants that are intended for anterior interbody screw fixation of the cervical spine during the development of a cervical spinal fusion. The Cardiff™ ACP System consists of a variety of shapes and sizes of bone plates, screws, and associated instruments. Cardiff™ ACP System implants are manufactured from Titanium 6AL-4V ELI and Nitinol SE508. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach.
Intended Use:	This system is indicated for use in the temporary stabilization of the anterior spine from C2 to C7 during the development of cervical spinal fusions in patients with: degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies, trauma (including fracture or dislocation), spinal stenosis, cervical myelopathy, deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and/or failed previous fusion.
Substantial Equivalence:	Cardiff™ was shown to be substantially equivalent in whole or in part to the following commercially available predicate device(s): • SeaSpine Sonoma™ Anterior Cervical Plate System (510(k) number K032368)

- Blackstone™ Anterior Cervical Plate system (510(k) number K974885)
- Medtronic Sofamor Danek Zephir™ system (510 (k) number K994239)
- Synthes CSLP System (510(k) numbers K926453, K945700 and K000536)

Performance Data: Mechanical testing results indicated that Cardiff™ possessed appropriate properties for its intended use and is substantially equivalent to predicate device(s). Clinical data was not required for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2009

SeaSpine Inc.
% Ms. Ethel Bernal
Regulatory Affairs Manager
2302 La Mirada Drive
Vista, California 92081-7862

Re: K083338
Trade/Device Name: Cardiff™ Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Anterior cervical system
Regulatory Class: II
Product Code: KWQ
Dated: November 10, 2008
Received: November 13, 2008

Dear Ms. Bernal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Cardiff™ Anterior Cervical Plate System

Indications for Use:

This system is indicated for use in the temporary stabilization of the anterior spine from C2 to C7 during the development of cervical spinal fusions in patients with:

- degenerative disc disease (DDD) as defined by back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies,
- trauma (including fracture or dislocation),
- spinal stenosis,
- cervical myelopathy,
- deformities or curvatures (*i.e.*, scoliosis, kyphosis, and/or lordosis),
- tumor,
- pseudoarthrosis, and/or
- failed previous fusion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083733